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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,647	12/07/2001	Markku Jalkanen	1708.0280002/MCA/MBT	9088
26111	7590	05/04/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,647

Applicant(s)

JALKANEN ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group XIV, claims 1-11 and 15-18 limited to a polynucleotide encoding a polypeptide of amino acids 1-618 of Figure 3 in the paper filed 4/5/04 is acknowledged. The traversal is on the ground(s) that the search would not be undue in that a "search for a polynucleotide that encodes a polypeptide at least 80% or 95% identical with amino acids 1-618 of Figure 3 will also identify fragments of the polypeptide sequence that possess the appropriate sequence identity". They further urge that if all the groups are not rejoined, at least Group XI should be rejoined with elected Group XIV since a "search of the whole sequence of amino acids 1-618 of Figure 3...will also reveal any hits against the same level of homology but against amino acids 34 to 154 of Figure 3...[and that] there would not be an undue search burden". This is not found persuasive because to search all of the embodiments of the instant claims would involve 14 different sequence searches, involve different 35 USC § 101 and 112 issues and it is maintained would be an undue burden. Even searching Group XI would not only involve searching an additional nucleotide sequence but would entail entirely different 35 USC § 101 and 112 first paragraph matters. Therefore the search would be an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-14 and claims 1-11 and 15-18 not limited as discussed *supra* are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 4/5/04.

The disclosure is objected to because of the following informalities:

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The amino acid sequence in Figure 3 is referred to in the claims and throughout the specification, but there is no apparent identification of this sequence as to SEQ ID NO in the specification. In a telephone conversation with Ms Michelle A. Cimbala of 4/15/04, it was determined that Figure 3 discloses the polypeptide sequence of SEQ ID NO:2 and that the corresponding polynucleotide sequence is SEQ ID NO:1. This SEQ ID NO must be added to the claims, either eliminating or retaining the reference to Figure 3. In addition, the sequences in Figure 1-2, 4-5 and 6B are not identified as to SEQ ID NO. The SEQ ID NO of these figures must be added (37 CFR § 1.821 - 1.825) and it is suggested that they be added to the Brief Description Of The Figures on pages 5-6 instead of to the figures themselves. Apparently there must be additional sequences added to the CRF disclosure.

It is stated in the description of Figure 1 on page 4 and in paragraph 117 that the bovine epimerase is in non-bold and the N-terminus of the mouse epimerase is in bold letters. Bold letter are not apparent when one looks at Figure 1, however some of the residues are underlined and others are not.

Figure 4 is objected to as being too dim to read and also the letters covered by the dark lines cannot be read at all. Also it is not known what is meant by the recitation in paragraph 22 that the "scores are shown on the top line and are listed in the column after the source of the sequence". There appears to be a bar graph on the top line, the meaning of which is not known, and there does not appear to be anything "listed in the column after the source of the sequence".

In Figure 5 "solid" and "hatched" boxes cannot be distinguished from one another.

What is in the lanes of Figure 9 are not readily discernible. There is not enough contrast with the background to tell what is in the lanes.

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Appropriate correction is required.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because it contains portions that were not elected for prosecution.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding an amino acid sequence that is 100% identical with residues 1-618 of SEQ ID NO:2, does not reasonably provide enablement for a polynucleotide encoding an amino acid sequence that is 95% identical. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches a polynucleotide encoding an amino acid sequence of SEQ ID NO:2, it does not teach one encoding an amino acid sequence that is 95% identical to SEQ ID NO:2. It is well known in the prior art that changes in the amino acid sequence of an enzyme may effect its activity and without in further guidance than what is in the instant specification, the

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claims should be limited to the polynucleotide encoding residues 1-618 or SEQ ID NO:2.

Claims 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for attaching a polynucleotide encoding residues 34-154 of SEQ ID NO:2 to the polynucleotide encoding bovine epimerase such that the first encoded polypeptide is in reading frame and attached to the N-terminus of the second encoded polypeptide, does not reasonably provide enablement for the scope of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant specification teaches that when a polynucleotide encoding residues 34-154 of SEQ ID NO:2 is attached in frame to the polynucleotide encoding the bovine epimerase, such that residues 34-154 of SEQ ID NO:2 are placed at the N-terminal end of the bovine epimerase, the activity of the expressed protein is increased. It does not teach that this polynucleotide can encode a protein that is 80% identical to residue 34-154 or 35-154, are residue 35-154 or that the polynucleotide can be attached such that it is not in reading frame. It is well known in the prior art that exactly what effect a change in an enzyme's sequence has on the activity of the enzyme is not predictable and therefore the instant claims should be limited to the embodiment that was shown to increase activity.

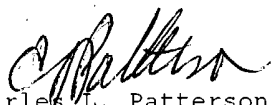
Li, et al. (U) is cited as of interest.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
April 28, 2004